Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2007437	06/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bright Pediatrics, Pc	2918 E Walnut Avenue, Dalton, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was performed on June 28, 2023. An entrance conference was held with the laboratory representatives. The survey process was discussed, along with review of the survey forms that was sent to the facility, previous to the survey. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficencies, but none were provided. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) Plan and interviews with the clinical manager and practice manager, the laboratory failed to follow the QA plan to review and monitor general laboratory systems quality assessment activities. Findings: 1. Review of the QA plan revealed the lab failed to follow the policy as written. "Quality indicators for the facility have been defined as, but not limited to: a. personnel qualifications,training, and performance evaluation b. periodic evaluation of physical environment for safety compliance c. monitoring of confidentiality of patient information d. monitoring of patient and specimen identification and integrity e. communication and complaint investigation f. evaluation of proficiency testing and split sample testing g. retention of records " 2. No documentation was available to

	review for the time period of August 2021 - June of 2023 3. Interviews with the clinical manager and the practice manager in the conference room on 6/28/23 at 12 Noon, confirmed the lack of documentation for the General Laboratory QA.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) Plan and interviews with the clinical manager and practice manager, the laboratory failed to follow the QA plan to review and monitor pre-analytic laboratory systems quality assessment activities. Findings: 1. Review of the QA plan revealed the lab failed to follow the policy as written. "Quality indicators for the facility have been defined as, but not limited to: a. test tracking (requisitions) b. speciamen handling, collection, and labeling c. specimaen referral process" 2. No documentation was available to review for the time period of August 2021 - June of 2023 3. Interviews with the clinical manager and the practice manager in the conference room on 6/28/23 at 12 Noon, confirmed the lack of documentation for the Pre-Analytic Laboratory QA.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on Cell-Dyn Emerald calibration document review and interviews with the clinical manager and the practice manager, the lab failed to calibrate the Cell-Dyn

	Emerald analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of the Cell-Dyn Emerald calibration data for the years of 2021, 2022, and 2023 (to date) revealed the Emerald was calibrated 6/20/21, 5/26/22 (an eleven (11) month span), and 2/15/23, a nine (9) month span between calibrations. 2. Interview with the clinical manager and the practice manager on 06/28/2023 at 12:15 PM in the conference room, confirmed the time spans.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) Plan and interviews with the clinical manager and practice manager, the laboratory failed to follow the QA plan to review and monitor Analytic laboratory systems quality assessment activities. Findings: 1. Review of the QA plan revealed the lab failed to follow the policy as written. "Quality indicators for the facility have been defined as, but not limited to: a. review and update of procedure manual b. monitoring supply and storeage of reagents, test equipment, instuments, materials c. instruments, with verification of calibration, quality control, and maintenance d. review of reference ranges e. test records" 2. No documentation was available to review for the time period of August 2021 - June of 2023 3. Interviews with the clinical manager and the practice manager in the conference room on 6/28/23 at 12 Noon, confirmed the lack of documentation for the Analytic Laboratory QA.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) Plan and interviews with the clinical manager and practice manager, the laboratory failed to follow the QA plan to review and monitor Post-Analytic laboratory systems quality assessment activities. Findings: 1. Review of the QA plan revealed the lab failed to follow the policy as written. "Quality indicators for the facility have been defined as, but not limited to: a. result reporting, verification of records and procedure for corrected reports b. documentation and notification of critical values and turn-around time evaluation" 2. No documentation was available to review for the time period of August 2021 - June of 2023 3. Interviews with the clinical manager and the practice manager in the conference room on 6/28/23 at 12 Noon, confirmed the lack of documentation for the Post-Analytic Laboratory QA.